

Atty Docket ONYX1034-CON1
Serial No. 10/053,422

3

Claim 14 (new): A method as described in claim 13, where in said unusual mRNA processing profile from said suspect cell comprises lacking exons 2 and 3.

Claim 15 (new): A method as described in claim 14, where in said cancer cell is melanoma.

Claim 16 (new): A method of diagnosing if a suspect cell is a cancer cell, comprising the steps of isolating b-catenin cDNA from a normal cell and said suspect cell, and analyzing said cDNA from said normal and suspect cells, and diagnosing said suspect cell as a cancer cell if it has mutations in its cDNA that results in a reduced level of phosphorylation of b-catenin, compared to said cDNA from said normal cell.

Claim 17 (new): A method as described in claim 16, wherein said cDNA isolated from said suspect cell has a mutation compared to cDNA isolated from said normal cell, wherein the mutation causes the substitution of amino acids in b-catenin at positions selected from the group consisting of ser33, ser37, thr41 and ser45.--

Remarks

Applicants will address the Examiner's remarks in the order presented by the Examiner in the Office Action mailed May 2, 2003.

Claim Rejections-35 U.S.C. § 112, Second Paragraph

Claims 6-8 are rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. Specifically, the Examiner has stated that the Applicants should recite how the presence of stabilized b-catenin is determined, and how the presence or absence of stabilized beta-catenin is indicative of unwanted cell growth.

The Examiner will note that the Applicants have amended claim 6, and thus claims 7 and 8 by their dependency from claim 6, to state that the amount of stabilized b-catenin is

3

Atty Docket ONYX1034-CON1
Serial No. 10/053,422

4

determined, and that if the amount is elevated relative to a normal cell that the "suspect cell" being analyzed is a cancer cell. The Examiner will note that Applicants' Specification provides several assays for determining the amount of b-catenin. In addition, standard protein/immunoprecipitation assays are well known to skilled practitioners of this art, and are readily applied to determining the amount of stabilized b-catenin.

The Examiner will further note that Applicants use of the word "elevated" is not new matter and is found on page 10, line 24 of the their Specification.

Applicants believe that the amended claims satisfy §112, Second Paragraph, and respectfully request that the rejection premised thereon be withdrawn

Claim Rejections-35 U.S.C. § 112, First Paragraph

Claims 6-8 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with it is most nearly connected, to make and/or use the invention.

More specifically, the Examiner has stated that it would require undue experimentation to isolate b-catenin from different diseases of "unwanted cell growth," including from "blood, saliva, lymphoid fluid, and biopsy sample, etc, in vitro or in vivo."

The Examiner will note that Applicants have amended the claims to cancel "unwanted cell growth" and in its place substituted cancer cells. Applicants believe that this amendment should obviate the rejection.

Applicants claims do cover cancer generally, and it is respectfully submitted that a skilled practitioner of this art would know how to analyze cancerous cells for b-catenin levels. In this regard then, Applicants believe that the amended claims satisfy §112, First Paragraph

New Claims

The Examiner will note that Applicants have added new claims, claims 12-17, which claims cover mRNA and cDNA methods for diagnosing if a cell is a cancer cell based on mutations that result in the production of stabilized b-catenin.

4

Atty Docket ONYX1034-CON1
Serial No. 10/053,422

5


If the Examiner believes that an interview would expedite the prosecution of Applicants' patent application, the Examiner is encouraged to call the undersigned.

A Petition for Three Month extension of time is being filed concurrently with this response.

The Commissioner is authorized to charge any fees associated with this communication to Deposit Account No. 15-0615 for any matter in connection with this response, including any fee for extension of time, which may be required.

Respectfully submitted,

Date: November 3, 2003

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5

Atty Docket ONYX1034-CON1
Serial No. 10/053,422

6

Appendix

(showing amendments made to the claims)

Claim 6 (newly amended): A method of diagnosing a cell suspected of being a cancer cell for disease based on unwanted cell growth, comprising the steps of isolating stabilized b-catenin from said suspect cell and a normal cell, and determining the amount of b-catenin present in both said suspect and normal cells, and diagnosing said suspect cell as a cancer cell if the suspect cell exhibits elevated levels of stabilized b-catenin compared to the normal cell~~determining the presence of stabilized beta-catenin in said cells.~~

Claim 7 (original): A method as described in claim 6 wherein said ~~disease is~~ cancer cell is colon cancer.

Claim 8 (original): A method as described in claim 6 wherein said cancer cell is melanoma.

Please add the following new claims:

--Claim 12 (new): A method of diagnosing if a suspect cell is a cancer cell, comprising the steps of isolating b-catenin mRNA from a normal cell and suspect cell, and analyzing said mRNA from said normal and suspect cells, and diagnosing said suspect cell as a cancer cell if it has an unusual mRNA processing profile compared to said mRNA from said normal cell.

Claim 13 (new): A method as described in claim 12, where in said unusual mRNA processing profile from said suspect cell comprises lacking exon 2.

Claim 14 (new): A method as described in claim 13, where in said unusual mRNA processing profile from said suspect cell comprises lacking exons 2 and 3.

6

Atty Docket ONYX1034-CON1
Serial No. 10/053,422

7

Claim 15 (new): A method as described in claim 14, where in said cancer cell is melanoma.

Claim 16 (new): A method of diagnosing if a suspect cell is a cancer cell, comprising the steps of isolating b-catenin cDNA from a normal cell and said suspect cell, and analyzing said cDNA from said normal and suspect cells, and diagnosing said suspect cell as a cancer cell if it has mutations in its cDNA that results in a reduced level of phosphorylation of b-catenin, compared to said cDNA from said normal cell.

Claim 17 (new): A method as described in claim 16, wherein said cDNA isolated from said suspect cell has a mutation compared to cDNA isolated from said normal cell, wherein the mutation causes the substitution of amino acids in b-catenin at positions selected from the group consisting of ser33, ser37, thr41 and ser45.--

7